## Remarks

Claims 1 to 8 are pending.

The Examiner maintained the rejection of claims 1 to 8 under 35 U.S.C. § 112, first paragraph, as allegedly not enabling for prodrugs and solvates because of the "reasons of record".

In response, applicants again traverse the Examiner's rejections. The term "prodrug" and "solvate" are defined and fully enabled by the specification, *inter alia*, on pages 132 and 134 and well within the ability of one of skill in the art to make and use the claimed invention based on the disclosure. The formation of solvates generally is a common aspect of the solidification of organic compounds from solvents; absolute predictability that such solvates will form is not a requirement for enablement. Furthermore, in the course of explaining the rejection, the Examiner requires for enablement of the instant claims to compounds to go far beyond the making of the prodrug, that it must be metabolized in a human at a rate and extent to produce a second substance at a "physiologically meaningful concentration" and be "clinically effective". In short, the Examiner is requiring *in vivo* human clinical testing to enable the claims. Such high levels of experimental proof regarding questions of human clinical efficacy are properly the province of the FDA, not the PTO. Applicants note that the PTO has been repeatedly reversed for rejecting for lack of enablement claims directed to compounds having pharmaceutical and biological activity. *See* M.P.E.P. § 2107 (particularly §§ 2107.01 III/IV and 2107.03, discussing the relationship of the utility and enablement requirements and the role of the FDA) and § 2164 (particularly § 2164.06). Moreover, the enablement of "prodrug" and "solvate" do not require this showing and this has been recognized repeatedly by the PTO, which has allowed similar claims containing the term "prodrug" and "solvate" for related glucocorticoid mimetic applications by at least five different examiners, *see, e.g.*, U.S. Patent Nos. 6,858,627; 6,903,215; 6,960,581; 7,074,806; 7,186,864; and 7,189,758. The Examiner argues that the merits of these patents is not before the Examiner, however, these patents have both similar disclosure with regard to prodrugs and solvates and may involve related compounds and applicants are bring this fact to the Examiner's attention to obtain consistent treatment regarding examination.

Furthermore, the Board has considered some of these issues regarding such terms. For example, *Ex parte Gante*, Appeal No. 2000-0600 (Bd. Pat. App. & Int.

2000)(nonprecedential)(copy enclosed for the convenience of the Examiner) reversed the rejection of the term solvates under 35 U.S.C. § 112, second paragraph, for indefiniteness:

> According to the examiner (Answer, page 3) the "[s]cope of 'solvates' as recited in ... [the] claims is unknown." The examiner finds (id.) "[g]enerally not all solvents can form solvates with all compounds ... [and] it is not routine for any and every type of solvent for form solvate(s) with specific compounds." According to the examiner (Answer, page 4) "[i]n the absence of any guidance in the specification ... or in any relevant prior art, [ ]one cannot readily determine what is and what is not within the instant scope of solvates."
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> In response, appellants argue (Brief, page 3) "[t]hat all solvents cannot form solvates with all compounds is not seen to be relevant herein. The relevant inquiry is whether it would be known to one of ordinary skill in the art what solvents form physiologically acceptable solvates with the compounds of formula I." In this regard, appellants argue (Brief, page 4), with reference to Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986), "the selection of useful solvents and formation of solvates is highly routine in this art. Appellants need not provide in their specification a description of matter which is common and routine in the art. A 'patent need not teach, and preferably omits, what is well known in the art.'" According to appellants' (Reply Brief, page 2) "[b]ecause selection of the appropriate solvents for forming solvates was routine to one of ordinary skill in the art, the metes and bounds of the term were reasonably determinable using only ordinary skill in the art." We agree.

(Pages 8-9).

The Examiner may perhaps object that *Ex parte Gante* concerned an indefiniteness rejection. However, the fact remains that the Board in *Ex parte Gante* considered the basis for the rejection that such solvates may not form and the identity of the solvents was not specified (the same as the instant rejection) insufficient and did not impose any other 35 U.S.C. § 112 rejection. Applicants' review of the Board decisions in the Westlaw database that includes cases to January 1987 found many cases involving the appeal of claims containing the term "solvate" or "prodrug" but none of which was rejected by the examiner or the Board because these terms did not comply with 35 U.S.C. § 112 in any respect, with the exception of *Ex parte Gante*, where the Board reversed the examiner's rejection. Accordingly, applicants again respectfully request that the Examiner reconsider and withdraw these rejections.

Applicants respectfully submit that all the pending claims are allowable and therefore solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone

interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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